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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,769	08/17/2006	Ladislav Cvak	TEVGAL 3.3-020	2277

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WESTFIELD, NJ 07090

EXAMINER
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MABRY, JOHN

ART UNIT	PAPER NUMBER
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4133

MAIL DATE	DELIVERY MODE
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11/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/589,769	CVAK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	John Mabry	4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/17/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "extracting", in all occurrences in the claims is interpreted to be relative term which renders the claims indefinite. The term "extracting " is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What does Applicant intend by this term? For examination purposes, the Examiner will interpret this term to be "extraction". The proper recitation of said term should be "extraction".

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lek (GB 1,299,557 A) in view of Keating (Lecturer Notes, CHEMISTRY CM3101 - Natural Products Chemistry, Dept. of Chem./School of Pharm., Univ. of College Cork).

The instant applicant claims a process of isolating an ergot alkaloid from ergot in a process comprising of extracting ergot with a mixture that consists of toluene and ethanol to form a primary extract. The primary extract is extracted with an aqueous acidic solution, more specifically aqueous HCl, to transfer the ergot alkaloid from the primary extract. The pH of the acid aqueous layer is adjusted to above 7.0, and then subsequently extracted with toluene to transfer the ergot alkaloid from the aqueous solution to obtain a purified toluene extract. The solvent of the purified toluene extract was then partially evaporated and ergot alkaloid then crystallizes from solution. C<sub>5-8</sub>

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aliphatic hydrocarbon, more specifically hexanes, was added to the mixture to aid in crystallization and then collected.

### ***Scope & Content of Prior Art MPEP 2141.01***

Lek discloses a process for isolating ergot alkaloids, which comprises of extracting ergot with toluene, an organic, water miscible solvent. The ergot extract was then filtered through alumina then dissolved in ethanol then the toluene-ethanol extract was partially evaporated and ergot alkaloid then crystallized from solution. Excess petroleum ether (hexanes) was then added to aid in the crystallization and then collected (see page 1, lines 40-75).

### ***Differences between Prior Art & the Claims MPEP 2141.02***

Lek differs from instant invention in that Lek uses alumina to filter unwanted impurities of ergot and does not disclose an acid-base extraction to isolate the ergot alkaloid.

Keating teaches that solvents such as toluene and ethanol can be used to extract ergot alkaloids and that subsequent acid-base extraction methods can be employed to such as the use of aqueous acids and bases. More specifically, aqueous HCl extraction and alkali base extraction with calcium hydroxide in order to purify the alkaloid by repeated conversion from acid or base to salt and partitioning between organic and

aqueous phases. Keating also suggests the use of hexanes to assist in ergot purification (see pages 9-10).

***Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413***

It would be obvious to one of ordinary skill in the art at the time the invention was made to combine the ergot alkaloid isolation process of Lek (utilizing extraction of ergot with a toluene-ethanol mixture, concentrating the solvent mixture and adding hexanes to aid in the crystallization of ergot alkaloids) in combination with the teachings of Keating (the use acid-base extractions in combination with hexanes) to in order to extract ergot alkaloids from ergot. One of ordinary skill in the art at the time that the invention was made would have been further motivated to combine the use of said processes, because it would eliminate harmful environmental solvents such as halogenated hydrocarbons and efficiently extract beneficial ergot alkaloids from ergot.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cvak (Ergot: The Genus Claviceps, 1999).

The instant applicant claims a process of isolating an ergot alkaloid from ergot in a process comprising of extracting ergot with a mixture that consists of toluene and ethanol to form a primary extract. The primary extract is extracted with an aqueous acidic solution, more specifically aqueous HCl, to transfer the ergot alkaloid from the primary extract. The pH of the acid aqueous layer is adjusted to above 7.0, and then

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subsequently extracted with toluene to transfer the ergot alkaloid from the aqueous solution to obtain a purified toluene extract. The solvent of the purified toluene extract was then partially evaporated and ergot alkaloid then crystallizes from solution. C<sub>5-8</sub> aliphatic hydrocarbon, more specifically hexanes, was added to the mixture to aid in crystallization and then collected.

### ***Scope & Content of Prior Art MPEP 2141.01***

Cvak (1999) discloses a process for isolating ergot alkaloids, which comprises of extracting ergot with toluene and ethanol then extraction using a continuous extractor to achieve high yields of ergot alkaloids. Cvak (1999) also describes that the obtained extracts (toluene-ethanol extract mixture) are then subjected to liquid-liquid extraction using diluted acids where the ergot alkaloids were then transferred to the aqueous layer evaporated and ergot alkaloid then crystallized from solution. Cvak (1999) continues to describe the purification of ergot alkaloids through crystallization through both bases and salts from different solvents (see pages 375-376).

### ***Differences between Prior Art & the Claims MPEP 2141.02***

Cvak (1999) describes the entire process of isolating ergot alkaloids as claimed. However, the crystallization of extracted ergot alkaloids from hexanes was not fully described. Lek describes the process of utilizing extraction of ergot with a toluene-ethanol mixture, concentrating the solvent mixture and adding hexanes to aid in the crystallization of ergot alkaloids.

***Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413***

It would be obvious to one of ordinary skill in the art at the time the invention was made to combine the ergot alkaloid isolation process of Cvak (1999) in combination with the teachings of Lek (utilizing extraction of ergot with a toluene-ethanol mixture, concentrating the solvent mixture and adding hexanes to aid in the crystallization of ergot alkaloids) to in order to extract ergot alkaloids from ergot.

One of ordinary skill in the art at the time that the invention was made would have been further motivated to combine the use of said processes, because it would eliminate harmful environmental solvents such as halogenated hydrocarbons and efficiently extract beneficial ergot alkaloids from ergot.

Additionally, the adjustment of particular conventional working conditions (e.g. determining result effective amounts of the ingredients beneficially taught by the cited references, especially within the broad ranges instantly claimed such as solvent ratios and quantity of acid used), as well as adjustment of reaction temperature, reaction time and use of solvents, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan (*In re* Mostovych, Weber, Mitchell and Aulbach, 144 USPQ 38). Accordingly, these types of modifications would have been well within the purview of the skilled artisan and no more than an effort to optimize results.



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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### Conclusion

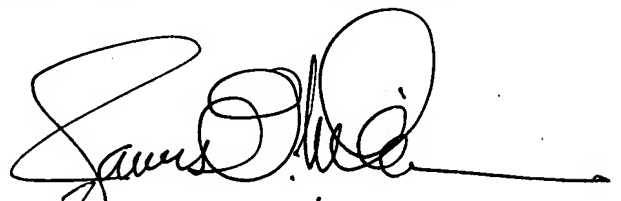
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



JM



James O. Wilson  
Supervisory Patent Examiner